

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The FDA Review Process for New Product Applications: An Interactive Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

DMB

Display Date	<i>6-29-00</i>
Publication Date	<i>7-5-00</i>
Certifier	<i>SNReese</i>

The Food and Drug Administration (FDA), Los Angeles District Office, in cosponsorship with the Orange County Regulatory Affairs Discussion Group (OCRA) is announcing a workshop intended to give the medical products industry (drugs and medical devices) an opportunity to learn and discuss the process by which the FDA centers and district offices review new product applications. Reviewing staff from the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health will make presentations to provide guidance on the elements of submissions to make the review process more effective.

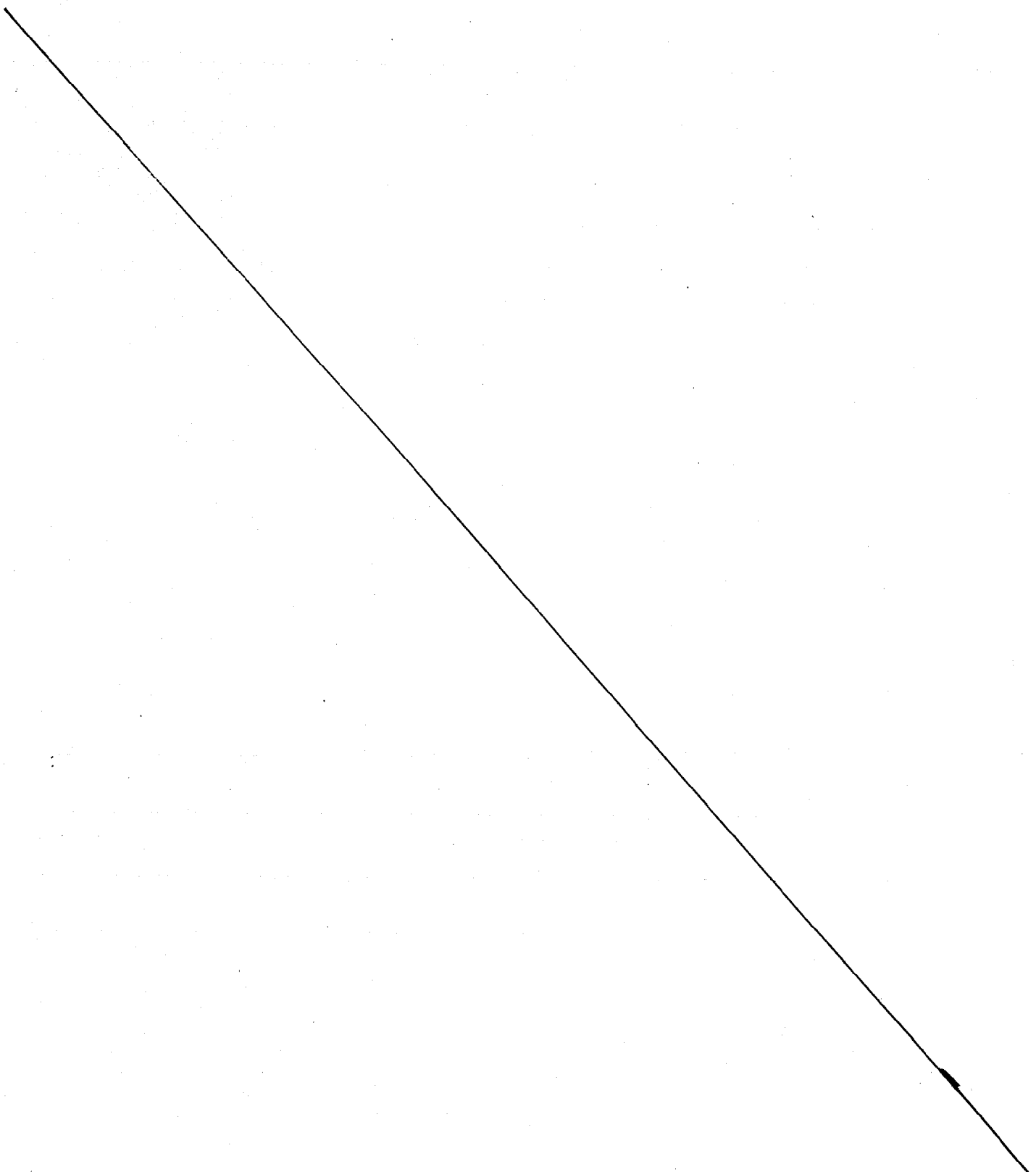
Date and Time: The workshop will be held on July 10 and 11, 2000, from 7:30 a.m. to 5 p.m.

Location: The workshop will be held at the Doubletree Hotel, 3050 Bristol St., Costa Mesa, CA 92626.

Contact: Ramlah Oma, FDA Los Angeles District Office, 19900 MacArthur Blvd., Irvine, CA 92612-2445, 949-798-7612, or FAX 949-798-7771, for further information including a registration form.

Registration: Space is limited. Preregistration and confirmation is required. Registration forms can be obtained on the Internet at <http://www.ocra-dg.org> by clicking on "OCRA Meetings" or from the contact person listed above. There is a \$325 registration fee if postmarked by June 30, 2000 (\$375 on or after July 1) payable to OCRA. Send the registration fee and form to PeriAnn DiRocco at OCRA Submissions Conference, PMB 624, 5405 Alton Pkwy., suite 5A, Irvine, CA

92604, FAX and voice 949-348-9141. The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. After July 4, 2000, please call 949-348-9141 to check for space availability.



If you need special accommodations due to a disability, please contact Ramlah Oma at least 7 days in advance.

Dated: June 28, 2000



William K. Hubbard,
Senior Associate Commissioner
for Policy, Planning, and Legislation.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

